UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re LANTUS DIRECT PURCHASER ANTITRUST LITIGATION	Civil Action No. 16-cv-12652 Leave to file granted on Mar. 12, 2018 (ECF No. 53)

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT SANOFI-AVENTIS U.S. LLC'S
MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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I. INTRODUCTION

Plaintiffs FWK Holdings, LLC, and Cesar Castillo, Inc. (collectively "Plaintiffs") have added more than fifty new pages to their Second Amended Complaint, but the pleading is so replete with legal argument that it would more accurately be captioned as a Motion for Reconsideration. Because the Second Amended Complaint fails to allege any well-pleaded facts that would render the Court's order dismissing the First Amended Complaint inapplicable, the Court should respect the law of the case and dismiss Plaintiffs' claim that defendant Sanofi-Aventis U.S. LLC ("Sanofi" or "Defendant") engaged in a scheme to delay competition for Lantus® and Lantus SoloSTAR® insulin glargine products.

First, the Court dismissed Plaintiffs' claim that the '864 patent was improperly listed in the Food and Drug Administration ("FDA") list of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), and declined to adopt Plaintiffs' interpretation of statutory and regulatory provisions describing patents that must be included in the Orange Book. The Court also rebuffed Plaintiffs' attempt to recast the Lantus SoloSTAR, a pre-filled drug delivery system, as mere "packaging" that would render the '864 and other pen patents ineligible for listing in the Orange Book. Plaintiffs' new listing allegations are purely argumentative and flatly misrepresent the contents of judicially noticeable documents. They cannot provide a basis for revisiting the Court's conclusion that listing a pen patent in the Orange Book was not anticompetitive.

Second, the Court dismissed Plaintiffs' claim that Sanofi engaged in sham litigation against Eli Lilly & Company ("Lilly") in light of Plaintiffs' own allegations that the litigation was hard fought, involved contested claim construction proceedings, and ultimately resulted in a settlement by which Lilly agreed to pay Sanofi for a license to market and sell Basaglar in Lilly's KwikPen device. Those allegations have not materially changed in the Second Amended

Complaint and compel the same outcome. Moreover, the Court dismissed Plaintiffs' sham litigation claim for failure to allege anything more than a conclusion that the Lantus SoloSTAR and Lilly KwikPen were "different." Plaintiffs repeat this assertion, and attempt to bolster their claim by contending that Sanofi could have sued Lilly in 2011 for a patent it did not obtain until 2013, and by comparing Lilly's '132 patent on the KwikPen to Sanofi's '864 patent on the SoloSTAR. The former makes no factual sense, and the latter (which compares one patent to another rather than a product to a patent) does not address infringement at all. The Second Amended Complaint still lacks any facts to support Plaintiffs' conclusory allegation that the KwikPen did not infringe any of Sanofi's patents, and still cannot state a sham litigation claim.

Third, so long as any one or more valid, properly listed, and reasonably litigated patents independently and lawfully barred the sale of competing insulin glargine products, Plaintiffs' claims fail for lack of causation. Indeed, the Court already held that the '864 pen patent "stood as a lawful bar to Lilly's market entry for so long as it remained in effect" and dismissed the First Amended Complaint for lack of causation. Nothing in the Second Amended Complaint alters this conclusion.

Finally, Plaintiffs' assertions that Lantus alone constitutes a relevant market and conclusory allegations of direct evidence of monopoly power are insufficient to state a claim for monopolization or attempted monopolization. Because this is the second time Plaintiffs have failed to cross the pleading threshold for a Sherman Act claim, the complaint should be dismissed with prejudice. *See Advanced Ion Beam Tech., Inc. v. Varian Semiconductor Equip. Assocs., Inc.,* 721 F. Supp. 2d 62, 64 (D. Mass. 2010).[1]

[1] *See also L'Esperance v. HSBC Consumer Lending, Inc.*, No. 11-CV-555-LM, 2012 WL 2122164, at *6 (D.N.H. June 12, 2012) (dismissing counts with prejudice where plaintiff "has already had two bites at this apple"); *see also In re Biogen Inc. Sec. Litig.*, 857 F.3d 34, 46 (1st Cir. 2017) (discouraging "any expectation that there will be leisurely repeated bites at the apple" (internal citation omitted)).

II. FACTUAL AND PROCEDURAL BACKGROUND

This case arises in the context of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (commonly known as the "Hatch-Waxman Act").

A. Statutory and Regulatory Background

As the Court explained in its Order dismissing the First Amended Complaint, the FDCA imposes certain requirements on brand name drug manufacturers seeking approval to market and sell drug products in the United States. *In re Lantus Direct Purchaser Antitrust Litig.*, No. CV 16-12652, slip. op. at 5-6 (D. Mass. Jan. 10, 2018), ECF No. 40 ("Order"). Among other things, the law mandates that a brand name drug manufacturer submit safety and efficacy data to FDA, as well as information about patents that "claim[ ] the drug for which the applicant submitted the application . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Id.* at 5; *see also* Second Am. Compl. ¶ 45. The FDA publishes information about these patents in the Orange Book to inform potential competitors about the "scope of the brand's ostensible patent protection." Order at 6; *see also* Second Am. Compl. ¶ 74.

The Hatch-Waxman Act amended the FDCA to facilitate the approval of lower-cost alternatives to brand name drugs. Order at 6; *see also* Second Am. Compl. ¶ 35. Under the Hatch-Waxman Act, competing drug manufacturers may rely on data developed by the brand name manufacturer, provided that the would-be competitor certifies the relationship between the proposed product and any patents listed in the Orange Book. Order at 6; *see also* Second Am. Compl. ¶ 73. If the competing drug manufacturer believes that its product "will not infringe a patent or that the relevant patent is invalid," it must serve the brand name manufacturer with a so-called "Paragraph IV certification" that constitutes a technical act of infringement under the

Patent Act, 35 U.S.C. § 271(e)(2)(A). Order at 7. If the brand name manufacturer sues the competing manufacturer within 45 days of receiving a Paragraph IV certification, the FDA may not approve the competing drug application until the earlier of 30 months or the end of the litigation. *Id*.

As this Court is well aware, this case concerns the types of patents that must be listed in the Orange Book pursuant to 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53 (collectively, the "Listing Provisions"). When FDA revised Section 314.53 in 2003, it attempted to clarify the rule in response to comments that "distinguished between packaging" (for which patents must not be listed in the Orange Book) and "devices such as metered dose inhalers and transdermal patches, which are drug delivery systems used and approved in combination with a drug" (for which patents must be listed). Order at 8 (citing *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a New Drug is Invalid or Will Not Be Infringed*, 68 Fed. Reg. 36,676, 2003 WL 21391636, at 36,680 (June 18, 2003) ("FDA Response")). FDA explained that "patents claiming a package or container must not be submitted" because they "are distinct from the drug product and thus fall outside of the requirements for patent submission." Order at 8 (citing FDA Response at Cmt. 3). But FDA went on to say that if the patent claims a "drug product," defined in the FDA Response to include finished dosage forms such as "pre-filled drug delivery systems," the patent "must be submitted for listing." *Id.*[2] Beyond these specific finished dosage forms, FDA noted that the "key factor is whether the patent being submitted claims the finished dosage form of the approved drug

[2] The FDA has since expressly cited "insulin injector pen[s]" as examples of "[p]refilled drug delivery systems." *See Frequently Asked Questions About Combination Products*, FDA, https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm#examples (last visited Mar. 16, 2018).

product. Patents must not be submitted for bottles or containers and other packaging, as these are not 'dosage forms.'" *Id.* at 8-9.

The FDA Response failed to address more nuanced questions about specific types of patents, including "patents claiming devices or containers that are integral to the drug product or require FDA approval," that must be listed in the Orange Book, and the agency has not responded to multiple requests for clarification in the thirteen years since the first of four such requests was filed (see *infra* Section IV.A.2).

B. The First Amended Complaint

According to the First Amended Complaint, Sanofi engaged in a two-part "scheme" to unlawfully extend its alleged monopoly over the sale of insulin glargine products. First, Plaintiffs contended that Sanofi collected a variety of patents—including composition ('722), formulation ('652 and '930), and pen ('044 and '864) patents—and indiscriminately listed them in the Orange Book as a means to delay follow-on competition for Lantus and Lantus SoloSTAR. *See generally* Compl. ¶¶ 103-37, 159-66. Plaintiffs asserted that improperly listing these patents in the Orange Book required Lilly to (1) notify Sanofi of its pending drug application for Basaglar; and (2) provide a Paragraph IV certification that the formulation and pen patents listed in the Orange Book were invalid, unenforceable, and/or would not be infringed by Lilly's insulin glargine product. *See generally* Compl. ¶¶ 180-81, 196-204. Plaintiffs alleged that Lilly complied with its Paragraph IV obligations in mid-December 2013, and additionally informed Sanofi about the "type" of its injector pen for insulin glargine, which was purportedly "different" from the Lantus SoloSTAR. Compl. ¶¶ 197, 204, 232.

Second, Plaintiffs alleged that Sanofi sued Lilly for infringement of the formulation and pen patents on January 30, 2014—triggering the automatic 30-month stay of FDA approval for Basaglar—even though there was purportedly no merit to the infringement claims. Compl.

¶¶ 205-06. According to Plaintiffs, the litigation progressed through "substantial discovery" over a 20-month period, during which the parties fought multiple discovery disputes; tendered experts; submitted *Daubert* motions; and undertook the "nuanced and complex process of claim construction." Compl. ¶ 238. On September 28, 2015, the morning the trial was scheduled to begin, the parties settled the case with an agreement that required Lilly to pay Sanofi royalties for a license to manufacture and sell Basaglar in the KwikPen, and allowed Lilly to launch Basaglar on December 15, 2016. Compl. ¶¶ 241-42.

According to Plaintiffs, the alleged "scheme" enabled Sanofi to unlawfully extend its patent monopoly over the sale of insulin glargine products. Plaintiffs sought to represent a putative class of direct purchasers who, as a consequence of this allegedly unlawful conduct, paid higher prices for Lantus between February 2015 (when the '722 patent's exclusivity ended), and December 15, 2016 (when Lilly launched Basaglar pursuant to the settlement and consent judgment). Compl. ¶¶ 105, 242-44, 284.

C. The Order Dismissing the First Amended Complaint

The Court dismissed the First Amended Complaint because Plaintiffs failed to plead that Sanofi employed an improper means of acquiring or maintaining monopoly power by listing and enforcing the '864 patent, and therefore failed to establish causation between any alleged antitrust violation and damages. Order at 3, 31-32.

First, the Court found that listing the '864 patent in the Orange Book did not constitute an illegal means of acquiring monopoly power because the "FDA has expressly interpreted 'drug products' which must be listed in the Orange Book to include 'pre-filled drug delivery systems'" such as the Lantus SoloSTAR. *Id.* at 20. In reaching that conclusion, the Court explicitly rejected Plaintiffs' argument (repeated in the Second Amended Complaint) that the Lantus SoloSTAR was merely "packaging," and that listing the '864 patent "was improper because [it]

did not 'claim[] the finished dosage form of the approved drug product.'" *Id.* at 11. Even if, as Plaintiffs contended, a "claim" concerning the drug product "must be made in the patent," the Court held that it was "not clear whether or not the 'claims' of the '864 patent, which are for a drug delivery device which includes a dose dial sleeve and a dose limiting mechanism, among other things, are sufficient to satisfy any such requirement." *Id.* at 21.

Further, the Court observed that the FDA Response was ambiguous, and did not directly address the "status of all 'patents claiming devices or containers that are 'integral' to the drug product or require prior FDA approval.'" *Id.* at 8 n.5.[3] Consequently, the "FDA caused confusion in the drug industry as to what types of product patents should be listed" in the Orange Book, *id.* at 8, prompting no fewer than four drug manufacturers to ask the FDA for clarification of its prior guidance.[4] The fact that the FDA has not responded in substance to the manufacturers' requests or otherwise clarified "whether a patent for a delivery system must claim 'the finished dosage form of the approved drug product,'" precluded a finding that there was no basis for listing the pen patents in the Orange Book. *Id.* at 24.[5]

Second, the Court held that enforcing the '864 patent in litigation with Lilly was not an illegal means of maintaining monopoly power. Plaintiffs' conclusory allegations that Lilly's "KwikPen was 'different' than and was not the same 'type' as the Lantus SoloSTAR" were insufficient to show that the patent litigation lacked objective merit. *Id.* at 13.

[3] The Court also observed that "Lantus SoloSTAR is clearly not just a package, or container to hold a drug, but rather is an integral part of the way insulin glargine can be used to treat diabetes." Order at 20-21.

[4] In addition, the Court expressed its view that "an argument can be made that listing the Lantus SoloSTAR and its components is consistent with the purposes of the Orange Book, which is to put others on notice of potentially relevant patents. As plaintiffs have alleged in the Amended Complaint, Lilly's competitive products included both a drug and a drug delivery system. Therefore, the patents relating to the drug delivery system would be relevant to determining whether Lilly's products were subject to patent infringement claims." Order at 20.

[5] Though the Court referenced what "Sanofi knew or should have known," Order at 24, the Court's Order makes clear that the pertinent legal question is whether a plausible reading of Listing Provisions and FDA Response provided a reasonable basis for the Orange Book listing, *see, e.g.*, Order at 19 (citing *Organon Inc. v. Mylan Pharm., Inc.,* 293 F. Supp. 2d 453, 460 (D.N.J. 2003)).

Moreover, the Court concluded that the combination of five particular facts would "defeat any contention that the litigation was objectively unreasonable" in any event. *Id.* at 28. Specifically, the Court noted that (1) Sanofi was enforcing patents that had never been invalidated or found unenforceable, *id.*; (2) the Paragraph IV certification was "an obvious act of infringement," *id.* at 28-29; (3) there would have been no reason for the court to conduct a claim construction exercise if the KwikPen "was completely different and bore no relationship to the Lantus SoloSTAR (as plaintiffs allege)," *id.* at 29; (4) the patent litigation was heavily contested for more than a year and a half before settling at the eleventh hour, *id.*; and (5) the settlement on terms favorable to Sanofi shows that "the underlying suit did not lack any merit," *id.* at 29-30.

Because Plaintiffs failed to plead facts showing that listing the '864 patent in the Orange Book was improper or that enforcing the '864 patent was a sham, "the '864 patent stood as a lawful bar to entry" until 2024. *Id.* at 32. Thus, even if Plaintiffs' allegations regarding the other patents were true, Plaintiffs had "no plausible argument for causation" because the '864 patent lawfully precluded competition well beyond the period of alleged harm. *Id.*

D. Plaintiffs' Second Amended Complaint

The core of Plaintiffs' claims in the Second Amended Complaint is essentially the same as the core of the claims the Court has already dismissed: namely, Plaintiffs contend that Sanofi employed an improper means of acquiring or maintaining monopoly power by listing and enforcing patents to unlawfully exclude competitors from the insulin glargine market.[6] Like the First Amended Complaint, the Second Amended Complaint appears to reflect a form of "pasta pleading" by which Plaintiffs have thrown a pot full of spaghetti against the wall to see whether

[6] For the Court's convenience, a copy of the Second Amended Complaint, redlined to show the differences between it and the First Amended Complaint, is attached as Exhibit A to this memorandum.

any strands might stick. Plaintiffs' second batch of pasta added more strands to the pot but no more to the wall.

As the following chart shows, Plaintiffs have added more than *50 pages* of text to their pleading, but they have not added *any* facts to affect the Court's prior conclusion that Plaintiffs cannot state a claim that Sanofi unlawfully delayed competition for Lantus and Lantus SoloSTAR products. Instead, Plaintiffs have added recycled legal arguments concerning their interpretation of the Listing Provisions and the FDA Response; blatant misrepresentations concerning the FDA's approval package for the Lantus SoloSTAR and industry requests for clarification of the FDA Response; and conclusory, immaterial, and irrelevant allegations that do not bear on the objective merit of Sanofi's infringement litigation with Lilly or ongoing Hatch-Waxman cases Sanofi filed against Merck Sharp & Dohme Corp. ("Merck") and Mylan N.V. and its affiliates (collectively, "Mylan") to enforce Lantus and Lantus SoloSTAR patents.[7]

New Allegations	Added Volume	Added "Value"
¶¶ 8, 46-50, 54, 57-70, 83-125, 255-77	21 pages	Legal argument about application of FDA regulations to pen patents (which the Court already rejected, *see* Order at 20-21), and blatant misrepresentations regarding industry requests for clarification (which do not change the fact that regulations were ambiguous and left an open question whether certain drug delivery device patents must be listed in the Orange Book, *see* Order at 24).
¶¶ 3, 190, 200, 203-14	3 pages	Selective and highly misleading citations from the 2007 SoloSTAR Supplemental New Drug Application and references to the Lantus SoloSTAR as "packaging" throughout the Complaint (which cannot obscure the fact that FDA approved the Lantus SoloSTAR as a pre-filled drug delivery system that included drug and device components, *see* Order at 20).
¶¶ 11, 147, 150, 152-54,	4 pages	Immaterial allegations regarding Sanofi's acquisition of pen patents that Sanofi did not assert against Lilly (which have no

[7] The Merck litigation is pending in the District Court for the District of Delaware, *see Sanofi-Aventis U.S. LLC, et al. v. Merck Sharp & Dohme Corp.,* Civ. A. No. 16-cv-00812 (D. Del.), and the Mylan suit is pending in the District of New Jersey, *see Sanofi-Aventis U.S. LLC v. Mylan N.V., et al.*, Civ. A. No. 17-cv-09105 (D. N.J.).

New Allegations	Added Volume	Added "Value"
386-403		bearing on Plaintiffs' claim since the '864 patent stood as a lawful bar to entry in any event, *see* Order at 32), and immaterial legal argument regarding patent litigation counterclaims.
¶¶ 11, 404-24, 430-35	5 pages	Wholly conclusory allegations regarding Sanofi's suits against Mylan and Merck and its purported motive for filing them (which are irrelevant because Plaintiffs have not pleaded lack of objective merit to those suits and cannot reach subjective intent, *see* Order at 31).
¶¶ 132-36, 242-43, 284, 287-88, 425-29	4.25 pages	Immaterial allegations regarding formulation patents (which could not have caused antitrust injury because the '864 patent stood as a lawful bar to entry, *see* Order at 32).
¶¶ 289-98, 320-24, 436-43	4.25 pages	Conclusory and misleading allegations that Lilly litigation lacked objective merit because Sanofi "conceded" the products were different and did not sue when it obtained first pen patent in 2011 (which is belied by the allegation that Sanofi did not acquire '864 patent until October 2013 and sued shortly after receiving Lilly's Paragraph IV certification later that year, *see* Order at 4, 12-13).
¶¶ 5, 126-31, 158, 357, 384, 386-88, 444-50	4.25 pages	Conclusory assertions of sham litigation and immaterial allegations regarding Sanofi's ability to enforce patents outside of Hatch-Waxman framework and its motive not to do so (which the Court need not consider absent actionable allegations that litigation lacked objective merit, *see* Order at 31).
¶¶ 4, 13, 137-38, 145, 453, 458	1.25 pages	Irrelevant allegations regarding overcharge and damages (which have no bearing on and do not change the Court's prior conclusion that Plaintiffs fail to state a claim, *see* Order at 2, 17, 32).
¶¶ 244-45, 329-30, 332-44, 349, 357	3.75 pages	Conclusory allegations that it was unreasonable for Sanofi to think that Lilly infringed Sanofi's patents in light of different patent claims and different product features (which are immaterial to an infringement analysis and inconsistent with the litigation record, *see* Order at 25-27).
¶ 463	.25 pages	Immaterial and conclusory allegations regarding "differences" between Lantus and other insulin products (which do not inform the pertinent relevant market inquiry, which is the reasonable interchangeability of use).
TOTAL	***51 pages***	

III. LEGAL STANDARDS

When "considering the merits of a motion to dismiss [pursuant to Rule 12(b)(6)], the court proceeds in two steps. First, [it] 'isolate[s] and ignore[s] statements in the complaint that simply offer legal labels and conclusions or merely rehash cause-of-action elements.'" Order at 15 (quoting *Schatz v. Republican State Leadership Comm.*, 669 F.3d 50, 55 (1st Cir. 2012)). This step is critical, because "naked assertions" and statements that "merely offer legal conclusions couched as facts" need not be accepted as true. *Air Sunshine, Inc. v. Carl*, 663 F.3d 27, 30, 33 (1st Cir. 2011); *Maldonado v. Fontanes*, 568 F.3d 263, 268 (1st Cir. 2009) ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."). Second, the court will "'take the complaint's well-pled (*i.e.*, non-conclusory, non-speculative) facts as true, drawing all reasonable inferences in the pleader's favor, and see if they plausibly narrate a claim for relief.'" Order at 15 (quoting *Schatz*, 669 F.3d at 55). When making this assessment, "[t]he court may also consider 'implications from documents attached to or fairly incorporated into the complaint . . . facts susceptible to judicial notice . . . [and] concessions in plaintiff's response to the motion to dismiss." *Schatz*, 669 F.3d at 55-56 (internal quotations and citations omitted).

Ultimately, the inquiry "requires the reviewing court to draw on its judicial experience and common sense." *Germanowski v. Harris*, 854 F.3d 68, 72 (1st Cir. 2017) (internal quotation marks and citations omitted). The Court must ask whether the well-pleaded factual allegations, "'taken as true, . . . state a plausible, not merely conceivable, case for relief,'" Order at 16 (quoting *Carrero-Ojeda v. Autoridad de Energia Electrica*, 755 F.3d 711, 718 (1st Cir. 2014) (internal citations and quotations omitted)); *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) (Posner, J.) ("[S]ome threshold of plausibility must be crossed

at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase.").

A monopolization claim under Sherman Act § 2 requires plaintiffs to "demonstrate (1) that the defendant possesses monopoly power in the relevant market, and (2) that the defendant has acquired or maintained that power by improper means." Order at 16 (quoting *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 21 (1st Cir. 1990) (Breyer, C.J.)). A claim of attempted monopolization requires plaintiffs to show: (1) anticompetitive conduct, (2) undertaken with "a specific intent to monopolize," and (3) "a dangerous probability of achieving monopoly power" in the relevant market. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456, 459 (1993). To be actionable, "the acquisition and maintenance of [monopoly] power must be willful, rather than a result of legitimate means [to exclude competition] such as patents . . . ." Order at 17 (quoting *Boston Scientific Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 268 (D. Mass. 1997)); *see also SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws."). Finally, to recover damages, plaintiffs must also plead an injury caused by and attributable to the "anti-competitive aspect of the practice under scrutiny." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990); *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 19 n.18 (1st Cir. 2008) (same); *see also* 15 U.S.C. § 15(a).

IV. ARGUMENT

Despite more than 50 new pages of text, the Second Amended Complaint fails yet again to state an antitrust claim based on an improper Orange Book listing or sham patent litigation, to establish causation between any anticompetitive conduct and alleged harm, or to properly allege a relevant market.

A. The Second Amended Complaint Fails to State an Improper Orange Book Listing Claim

As the Court explained when it dismissed the First Amended Complaint, "[i]t is undisputed that 'listing presumptively valid patents in the Orange Book and enforcing them against infringers are not bases for an antitrust claim; Orange Book listing is a statutory obligation and enforcement is a statutory right.'" Order at 18 (citing *In re Lipitor Antitrust Litig.*, MDL No. 2332, 2013 WL 4780496, at *21 (D.N.J. Sept. 5, 2013) and *In re Solodyn (Minocylcine Hydrochloride) Antitrust Litig.*, No. 14-md-02503-DJC, 2015 WL 5458570, at *12 (D. Mass. Sept. 16, 2015)). While an improper Orange Book listing may subject a patent holder to antitrust liability, Order at 18 (citing *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 372-73 (S.D.N.Y. 2002)), a listing is not improper if a drug manufacturer "had a reasonable basis for the submission," Order at 19 (citing *Organon,* 293 F. Supp. 2d at 460). Nothing in the Second Amended Complaint provides a basis for revisiting the Court's prior conclusion that listing the '864 patent was proper given the ambiguity in FDA's regulations and could not provide the foundation for an antitrust claim. Order at 20-24.

Plaintiffs have doubled down on their theory that patents relating to components of insulin pen injectors may not be listed in the Orange Book. Plaintiffs' new allegations in support of that theory consist of argumentative assertions about how to construe Listing Provisions and blatant mischaracterizations of documents referenced in or attached to the Second Amended Complaint. The Court need not credit either. *See Schatz,* 669 F.3d at 55; *see also Maldonado,* 568 F.3d at 268. Where, as here, "the Second Amended Complaint contains no alleged facts that would render the [Court's prior] ruling inapplicable," the law of the case doctrine prescribes that the Court should "respect and follow its own ruling" and dismiss Plaintiffs' Orange Book claims. *Metro. Prop. & Cas. Ins. Co., et al., v. Savin Hill Family Chiropractic, Inc., et al.,* 266 F. Supp.

3d 502, 522 (D. Mass. 2017) (Dein, M.J.) (citing *Ellis v. United States*, 313 F.3d 636, 646 (1st Cir. 2002)).

1. The Second Amended Complaint Merely Repackages Legal Arguments the Court Has Already Rejected

Plaintiffs' amended Orange Book allegations purport to recite – but attempt to revise – the Listing Provisions. *See, e.g.*, Second Am. Compl. ¶¶ 46-50. These legal arguments masquerading as factual allegations are most obvious with respect to Plaintiffs' new assertions about the 2003 revisions to 21 C.F.R. § 314.53 and the FDA Response to comments about the revisions. *See id.* ¶¶ 54-70. For example, Plaintiffs allege that:

> FDA confirmed that "[f]or patents that claim a drug production, the applicant shall submit information *only on those patents that claim a drug product, as defined in §314.3*, that is described in the pending or approved application." Section 314.3 stated, "[d]rug product is a finished dosage form, e.g., tablet, capsule, or solution *that contains a drug substance* . . . ." Section 314.3 defines "drug substance" as "an *active ingredient* that is intended to furnish pharmacological activity or other direct effect . . . ." **Putting these three pieces together, the FDA's position was that – for patents that purportedly claimed a drug product – applicants shall submit information / request listing *only* for those patents that claim a finished dosage form that *contains the drug's active ingredient.***
>
> **The key language in 314.3 is "that contains the drug substance." This qualifier makes crystal clear that, for example, a patent claiming a new aspect of a tablet coating that does also claim a drug's active ingredient is not "a finished dosage form." As the canon of statutory and regulatory interpretation teaches, the phrase "that contains the drug substance" must be understood to have meaning. It cannot be presumed to be accidental or otherwise read out of the rule.**

Id. ¶¶ 59-60 (italics in original, bold emphasis added). The Court need not credit legal arguments garbed as allegations when considering the motion to dismiss. *See Cichocki v. Bank of Am.,* No. 12-CV-10441-NMG, 2013 WL 6859027, at *4 (D. Mass. June 24, 2013), *aff'd* (Dec. 2, 2014) (dismissing amended complaint where plaintiffs failed to "meaningfully supplement[] their factual allegations, as distinct from mere conclusory statements and legal argument"); *see*

also In re Colonial Mortg. Bankers Corp., 324 F.3d 12, 17 (1st Cir. 2003) (holding that "legal conclusion" asserted in a complaint "is not a factual allegation deserving of indulgence under Rule 12(b)(6)").

Nor must the Court revisit arguments it has already rejected.[8] The Court explicitly rebuffed Plaintiffs' claim that listing the '864 and other pen patents was improper because those patents did not explicitly "claim" insulin glargine. *Compare, e.g.,* Order at 24 (concluding that the FDA Response left an "open question" whether a "patent for a delivery system must claim 'the finished dosage form of the approved drug product'" and holding that listing the '864 patent reflected a reasonable interpretation of the Listing Provisions), *with* Second Am. Compl. ¶ 266 (arguing that "[t]here is no open question, or room to debate whether [the '864 patent]—which, as described below, d[id] not claim insulin glargine—could be submitted for listing in the Orange Book. The statute is clear. The regulations are clear. The FDA's explanation of its regulations is clear.").

The Court should not treat the Second Amended Complaint as a motion for reconsideration. In urging the Court to permit them to file a motion for leave to amend the First Amended Complaint, Plaintiffs expressly resisted the notion that the Order constituted a final judgment (from which a motion for reconsideration might properly be brought pursuant to Fed. R. Civ. P. 60(b)). Consequently, Plaintiffs are bound by the Order rejecting these arguments unless and until the Order is "corrected by an appellate tribunal," *Ellis,* 313 F.3d at 646; *see also Smith v. MacEachern*, Civ. A. No. 09-10434, 2017 WL 1173949 at *8 (D. Mass. Feb. 17, 2017)

[8] Indeed, Plaintiffs' futile amendment of their complaint borders on the frivolous to the extent it merely recycles arguments this Court already rejected. *See Chawla v. Pitter*, No. CV 14-14303-GAO, 2015 WL 6509119, at *2 (D. Mass. Oct. 28, 2015) ("Since the proposed complaint offers no new facts to support grounds for relief other than those already found meritless, amending the complaint would be futile."); *Salvioli v. Cont'l Ins. Co.*, No. C 96-0630, 1996 WL 507297, at *5 (N.D. Cal. Sept. 3, 1996) (imposing sanctions where the Second Amended Complaint was "frivolous" and asserted arguments "already rejected" by the court).

(Dein, MJ) (observing that the defendant "has not requested that the court reconsider this ruling, and there is no reason to do so" because a ruling of law "should continue to govern the same issues in subsequent stages in the same case" (citation omitted)).

2. The Second Amended Complaint Blatantly Misrepresents Industry Requests for Clarification of the FDA Response

After ignoring other drug manufacturers' requests for clarification of the Listing Provisions and FDA Response in the First Amended Complaint, Plaintiffs now devote 13 pages in the Second Amended Complaint to mischaracterizing the requests, impugning the manufacturers' motives for filing them, and taking issue with the Court's conclusions about the FDA's failure to respond to the substance of the requests after more than thirteen years. *See* Second Am. Compl. ¶¶ 83-125. For example, Plaintiffs contend that the requests "admitted" that the Listing Provisions did not permit drug manufacturers to list drug delivery device patents in the Orange Book, *id.* ¶ 120, and that the requests asked FDA to "change" the regulations to permit such listings, *id.* ¶ 88. The requests did neither, and Plaintiffs' mischaracterizations of the publicly available documents cited in their pleading are not entitled to a presumption of truth. *See Schatz,* 669 F.3d at 55; *see also Henning v. Wachovia Mortg., FSB*, 969 F. Supp. 2d 135, 147 (D. Mass. 2013) ("At the motion to dismiss stage this Court may take notice of public documents . . . which bear on the merits of [plaintiff's] claims. When such documents contradict allegations in the complaint, the documents trump the allegations." (internal citations omitted)).

It is no wonder that Plaintiffs want to discredit the requests for clarification, since the Court took judicial notice of and expressly relied on them in dismissing the First Amended Complaint. Order at 22 n.10, 22-24 (citing Fed. R. Evid. 201). As the Court explained in the Order, the requests highlighted the ambiguity inherent in the Listing Provisions and FDA Response, and asked FDA to clarify whether patents for drug delivery devices (including pre-

filled drug delivery systems) should be listed in the Orange Book if they do not claim the active ingredient contained in the drug product. *Id.* at 22-24.[9] If, as Plaintiffs contend, the answer to that question were as obvious as a speed limit sign posted on the Massachusetts Turnpike, *see* Second Am. Compl. ¶ 122, the FDA would have said so at some point in the thirteen years since the first request was filed in 2005. *See* 21 C.F.R. § 10.85(a)(2)(iii) (authorizing FDA to deny petitions outright if they are "adequately covered by a prior advisory opinion or a regulation"). It has not done so. Simply put, Plaintiffs' misleading allegations about the requests for clarification do not provide a basis for re-litigating the Order.

3. Plaintiffs Continue to Ignore the Undisputable Fact That Lantus SoloSTAR is a Pre-Filled Drug Delivery System

Remarkably, Plaintiffs still contend that that the Lantus SoloSTAR is merely "packaging," and that the '864 and other pen patents could not be listed in the Orange Book because the Listing Provisions and FDA Response explicitly state that "patents claiming a

[9] *See* Request for Advisory Opinion on behalf of GSK, Docket No. FDA-2005-A-0476 (Jan. 10, 2005), *available at* https://www.regulations.gov/document?D=FDA-2005-A-0476-0003, at 5-7 (noting "the lack of explicit guidance" and the "conflict between the various guidance statements made by the agency" and seeking "clear and explicit guidance from FDA" for NDA holders who "remain in a difficult position" because "FDA has yet to clearly define whether certain kinds of patents are or should be listed" in the Orange Book); Request for Advisory Opinion by Ropes & Gray, Docket No. FDA-2006-A-0063 (Aug. 10, 2006), *available at* https://www.regulations.gov/document?D=FDA-2006-A-0063-0005, at 2 ("FDA has not, however, directly addressed whether patents directed to drug delivery systems, such as inhalers that are approved along with the formulation, that do not recite the approved active ingredient or formulation should be listed in the Orange Book."); Request for Advisory Opinion on behalf of AstraZeneca, Docket No. FDA-2007-A-0099 (June 21, 2007), *available at* https://www.regulations.gov/document?D=FDA-2007-A-0099-0003, at 2 ("The FDA's endorsement of the [FDA Response's] distinction between packaging and drug delivery systems leaves certain questions unanswered and in need of further clarification. First, it remains unclear as to what types of products fall within the meaning of the term 'pre-filled drug delivery systems,' particularly when such products are not expressly identified in the definition of dosage forms or listed in Appendix C of the Orange Book."); Request for Advisory Opinion on behalf of Forest Laboratories, Docket No. FDA- 2011-A-0363 (May 12, 2011), *available at* https://www.regulations.gov/document?D=FDA-2011-A-0363-0001, at 3 ("However, guidance regarding compliance with the listing requirement is not clear when the patent claims a drug delivery device integral to the administration of the active ingredient but does not recite the active ingredient."); and Request for Advisory Opinion on behalf of Novo Nordisk, Docket No. FDA-2012-A-1169 (Nov. 26, 2012), *available at* https://www.regulations.gov/document?D=FDA-2012-A-1169-0001, at 3 ("FDA's distinction between pre-filled drug delivery systems and product packaging remains unclear, however, because the term 'pre-filled drug delivery systems' is not defined.").

package or container must not be submitted." *See* Second Am. Compl. ¶¶ 203-11, 61-63. Plaintiffs' factual premise is patently false and does not justify revisiting the Order.

Plaintiffs concede (as they must) that the FDA's approval letter described the Lantus SoloSTAR as a "disposable insulin injection device," but nonetheless insist that the FDA's treatment of the SoloSTAR Supplemental New Drug Application (SNDA) revealed that the agency considered the pen to be a "container" or "packaging." Second Am. Compl. ¶ 204. To reach that destination, Plaintiffs embark on a self-serving and unabashedly misleading tour of the FDA's approval package for the SNDA (attached to the Second Am. Compl. as Ex. N).[10] To be sure, correspondence between FDA and Sanofi and some internal agency memoranda in the approval package include the words "container" and "packaging." Second Am. Compl. ¶¶ 204-08. But those words cannot be divorced from the context in which they were used—namely, where to put the drug label—and do not have the dispositive significance Plaintiffs would have the Court attach to them.

Moreover, Plaintiffs ignore the fact that *every single document in the package refers to the Lantus SoloSTAR as a "drug-device combination," "device," "insulin pen delivery device," "insulin pen device," "insulin delivery device," or "insulin injector pen." See generally* Second Am. Compl. Ex. N. One memorandum, for example, described the SoloSTAR as "a disposable pen injector with the Lantus cartridges [containing the active ingredient] irreversibly integrated into the system." *See id.* at 68. Plaintiffs' "container" and "packaging" allegations to the contrary need not be credited. *See Yacubian v. United States*, 750 F.3d 100, 108 (1st Cir. 2014)

[10] The approval package described the Lantus SoloSTAR as a drug-device combination, *see* Second Am. Compl. Ex. N at 113, and includes internal and external communications concerning drug and device approval issues. For example, the package reflected the agency's evaluation of the drug label's content and placement to minimize the risk of medication errors, *see, e.g.*, *id.* at 68-75, 98-101, and an assessment of the device's ability to accurately and safely deliver selected doses of insulin glargine, *see, e.g.*, *id.* at 77, 82-86, 103-107.

(applying the "well-settled rule" that courts need not credit allegations contradicted by exhibits to the complaint).

Finally, it is telling that Plaintiffs make no mention of the fact that the FDA's combination product webpage *explicitly cites "insulin injection pen[s]" as examples of "prefilled drug delivery systems,"*[11] or of the fact that the Court has already rejected their "packaging" argument. Order at 20. Nothing in the Second Amended Complaint affects that conclusion, and the Orange Book claim should be dismissed with prejudice.

B. The Second Amended Complaint Fails to State a Sham Litigation Claim

This Court previously held that Plaintiffs' sham litigation assertions were unsupported by factual allegations and foreclosed by the underlying litigation record. Order at 26-31. Plaintiffs have thrown more conclusory assertions, misrepresentations, and irrelevant details into their complaint in an attempt to obscure its deficiencies. But Plaintiffs' second attempt is no more successful than the first, and Plaintiffs' sham litigation claims must still be dismissed.

1. Sanofi's Patent Litigation Against Lilly Was Not Objectively Baseless

As this Court explained, the first step in stating a sham litigation claim is adequately alleging that the defendant's "lawsuit [was] objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Order at 26 (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)); *see also id.*, 508 U.S. at 62-63 (explaining that a sham litigation claim is foreclosed if it was reasonable to believe "that there [was] a chance that a claim may be held valid upon adjudication"). Under this standard, sham litigation plaintiffs face an "uphill battle" under the best of circumstances, but when a

[11] *See Frequently Asked Questions About Combination Products*, FDA, https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm#examples (last visited Mar. 16, 2018). The FDA's statement, "published on a government website, constitutes a 'public record' of which the Court may take judicial notice." *Kader v. Sarepta Therapeutics, Inc.*, No. 1:14-CV-14318, 2016 WL 1337256, at *11 (D. Mass. Apr. 5, 2016) (collecting cases).

plaintiff claims that litigation triggered by a Paragraph IV certification is a sham, "[t]he already high hurdle for stating an antitrust claim for anticompetitive litigation is higher still . . . because . . . the submission of an ANDA is, by statutory definition, an infringing act." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 149 (3d Cir. 2017); *see also CBS Interactive Inc. v. Nat'l Football League Players Ass'n, Inc.*, 259 F.R.D. 398, 413 (D. Minn. 2009) ("The sham exception is 'narrow,' and [plaintiff], as the party attempting to invoke the exception, 'bears a heavy burden of demonstrating that the lawsuit is objectively meritless.'"). Plaintiffs have not cleared—and cannot clear—that high hurdle in this case.

(a) The Patent Litigation Record Precludes a Plausible Sham Litigation Claim

As this Court previously held, "the record in the underlying litigation establishes that Sanofi's contention that the KwikPen infringed on the '864 patent was not objectively baseless." Order at 29. Nothing in the Second Amended Complaint changes that reality.

Plaintiffs continue to acknowledge (as they must) that Sanofi's litigation against Lilly was preceded by an unambiguous statutory act of infringement in the form of a Paragraph IV certification. Second Am. Compl. ¶¶ 306-15, 325. This fact alone provided Sanofi with "an objectively reasonable basis to sue." *See AstraZeneca AB v. Mylan Labs., Inc.*, No. 00-CIV-6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010). Additionally, neither the First nor the Second Amended Complaint contends that the '864 patent was obtained by fraud or that it was found to be invalid or unenforceable.[12] A duly issued patent still "carr[ies] a presumption of validity," and Sanofi's assertion of the '864 patent was "presumed to be made in good faith." *Morton Grove Pharm., Inc. v. Par Pharm. Cos.*, Inc., No. 04 C 7007, 2006 WL 850873, at *11

[12] Plaintiffs allege that the '652 and '930 patents are the subject of an ongoing *inter partes* review by the Patent Trial and Appeal Board ("PTAB"). Second Am. Compl. ¶¶ 427-29. But Plaintiffs do not allege that either patent has been found invalid or unenforceable, or that the '864 patent (which, the Court held, stood as an independent and lawful bar to competition) has been subject to a PTAB challenge. *See id.*

(N.D. Ill. Mar. 28, 2006); *THK Am., Inc. v. NSK Ltd.*, 157 F.R.D. 660, 663 (N.D. Ill. 1994) (explaining that "a patent infringement suit is presumed to be brought in good faith," and "the presumption of the validity of patents provides [defendant] with a reasonable expectation that its patent infringement claims may be held valid upon adjudication").[13]

Nor do Plaintiffs dispute that Sanofi's litigation with Lilly was hard fought for over a year and a half, included a claim construction hearing that upheld a number of Sanofi's positions, and ended with a settlement that required Lilly to pay Sanofi patent royalties, just as trial was set to begin. Second Am. Compl. ¶¶ 372-73, 375; *see also* Order at 11-14. "Hard-fought and close" cases "hardly bespeak[] baseless litigation," *AstraZeneca*, 2010 WL 2079722, at *4, and courts have "invariably held that lawsuits terminating in a favorable settlement are . . . objectively reasonable and are not shams," *Toyo Tire & Rubber Co., Ltd. v. Atturo Tire Corp.*, No. 14 C 0206, 2017 WL 1178224, at *4 (N.D. Ill. Mar. 30, 2017).

This Court has already (and correctly) concluded that the Lilly litigation record precludes a plausible claim that Sanofi's suit against Lilly was objectively baseless. Plaintiffs' Second Amended Complaint contains no facts to undermine the factual bases for the Court's ultimate conclusion, and it provides no reason for this Court to revisit the Order. *See, e.g.*, *Metro. Prop.,* 266 F. Supp. at 522; *Smith*, 2017 WL 1173949, at *9.

[13] *See also United Food & Comm. Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, No. 15-CV-12732, 2017 WL 2837002, at *11 (D. Mass. June 30, 2017) ("A firm that has received a patent from the patent office (and not by fraud), and thus enjoys the presumption of validity that attaches to an issued patent is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think . . . the defendants were almost certain to be found not to have infringed it, if the suit went to judgment." (quoting *Asahi Glass Co.*, 289 F. Supp. 2d at 992-93)).

(b) Plaintiffs' Conclusory Allegations Fail to State a Plausible Sham Litigation Claim

This Court previously found Plaintiffs' allegation that Sanofi knew that Lilly's KwikPen was "different" from the mechanisms described in the '864 patent, Second Am. Compl. ¶¶ 365-67, was "insufficient to show that the underlying lawsuit lacked any reasonable merit," Order at 27. The Second Amended Complaint attempts—unsuccessfully—to fill this void in three ways: (1) by falsely claiming that Sanofi "concede[d] that KwikPen and SoloSTAR are very different"; (2) by baldly asserting that "[i]f Sanofi believed that Lilly's KwikPen infringed Sanofi's initial injector pen patents, it could have – and would have – sued Lilly once Sanofi obtained its first pen patents, in 2011"; and (3) by comparing excerpts of the '864 patent to Lilly's 7,291,132 ("'132") patent.[14] Second Am. Compl. ¶¶ 333-43, 436-42, 446. None of these allegations provides factual support for Plaintiffs' assertion that Sanofi's infringement claim lacked objective merit.

First, although Plaintiffs assert in a heading that Sanofi "conceded" that the SoloSTAR and KwikPen were "very different," the allegations under that heading say no such thing. Rather, Plaintiffs allege that Sanofi's Paragraph IV certification with respect to a different SoloSTAR product said Sanofi's product would not infringe Lilly's '132 patent—*not that Lilly's KwikPen product did not infringe Sanofi's '864 patent*. Second Am. Compl. ¶¶ 436-42. The two propositions are not interchangeable. The fact that Lilly did not sue Sanofi over its '132 patent says nothing about the objective merit of Sanofi's claim that Lilly's product infringed its '864 patent.

[14] The Second Amended Complaint also includes a number of entirely speculative and conclusory allegations unaccompanied by facts. *See, e.g.*, Second Am. Compl. ¶¶ 344, 386 (asserting that Sanofi "would have lost" at trial and that its lawsuit had no reasonable basis). These allegations are not entitled to a presumption of truth and are properly disregarded when analyzing a motion to dismiss. *Maldonado*, 568 F.3d at 268 ("Such conclusory statements are not entitled to the assumption of truth." (internal quotation marks omitted)).

Second, Plaintiffs claim that Sanofi "could have . . . sued Lilly once Sanofi obtained its first pen patents, in 2011" and failed to do so. Second Am. Compl. ¶ 446. But this is demonstrably false, and has no bearing on the objective reasonableness of Sanofi's subsequent suit.[15] Plaintiffs allege that the oldest pen patent asserted in Sanofi's suit against Lilly was the '864 patent, which issued on October 15, 2013. Second Am. Compl. ¶¶ 251, 325. Lilly filed its NDA "in late 2013," Sanofi received notice of Lilly's first Paragraph IV certifications on December 19, 2013, and Sanofi timely filed its suit on January 30, 2014. *Id.* ¶¶ 301, 308, 325. The fact that Sanofi did not assert the '864 patent against Lilly in 2011—*years before the '864 patent actually issued*—simply cannot support a plausible claim that Sanofi's timely suit against Lilly in 2014 was objectively baseless.[16]

Third, it is axiomatic that a patent infringement analysis requires a comparison of "the patent claims asserted" to "the allegedly infringing device." *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1369 (Fed. Cir. 2004). Plaintiffs have not even attempted such a comparison. Instead, the Second Amended Complaint contains conclusory allegations that the SoloSTAR and KwikPen have different benefits, Second Am. Compl. ¶ 245, and recites lengthy excerpts from the '864 and '132 patents, *id.* ¶¶ 333-43. Such product-to-product and patent-to-patent comparisons do not support Plaintiffs' contention that Sanofi had no basis for asserting that the KwikPen did not infringe the '864 patent, because "the only proper comparison is [of the

[15] Plaintiffs also suggest that failing to sue Lilly before 2014 indicated some sort of anticompetitive intent. But allegations of anticompetitive, subjective intent do not excuse plaintiffs from pleading facts that plausibly support a claim that a lawsuit was objectively baseless. *See AstraZeneca*, 2010 WL 2079722, at *6 n.3 (refusing to permit the case to proceed to discovery concerning patent holder's subjective motivation for bringing infringement suit absent plausible allegations that the suit was objectively baseless).

[16] Moreover, the fact that Sanofi did not sue Lilly on the '833 or '297 patents (which were listed in the Orange Book at the time Lilly sent Sanofi its Paragraph IV certification in 2013) underscores the point that Sanofi was not indiscriminately asserting patents against potential competitors. And if Sanofi had sued on those patents—either in 2011 when it obtained the '833 patent or in 2013 when it obtained the '297 patent—Plaintiffs would surely complain about that, too.

accused product] with the claims of the patent." *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) ("[I]t is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process . . . .").

Moreover, while a claim of sham litigation following a Paragraph IV certification "could only be objectively baseless if no reasonable person could disagree with the assertions of non-infringement," *In re Wellbutrin*, 868 F.3d at 149, Plaintiffs have failed to allege even a *plausible* claim of non-infringement, let alone a claim so strong that no reasonable person could disagree. Plaintiffs were required to do more than "stat[e] in conclusory terms that [the] accused product . . . meets the elements of non-infringement." *Comcast Cable Commc'ns, LLC v. OpenTV*, Inc., 319 F.R.D. 269, 273 (N.D. Cal. 2017). They were required to include "factual allegations showing *how* each accused product . . . specifically does not meet at least one claim limitation, such that it does not infringe the asserted patent . . . ." *Id.* (dismissing non-infringement claims based on "boilerplate language," summaries of "what the patent does," and "quotes [of] a relevant claim," where plaintiff did not "explain how any accused product . . . meets the claim limitations of a corresponding patent"); *see also Arctic Cat, Inc. v. Polaris Indus. Inc.*, No. CIV. 13-3579, 2014 WL 5325361, at *26 (D. Minn. Oct. 20, 2014) (dismissing conclusory sham litigation claim for failure to plead facts showing how the challenged product did not infringe patent at issue); *Mercer Publ'g, Inc. v. Smart Cookie Ink, LLC*, No. C12-0188, 2012 WL 12863934, at *5 (W.D. Wash. July 25, 2012) (holding that for "non-infringement [claims], the pleading must not only deny infringement, but must explain how specific products do not infringe"). Plaintiffs have not pleaded a factual basis for their assertion that Lilly's KwikPen does not infringe the '864 patent, and still cannot state a sham litigation claim.

2. Conclusory and Unsupported Allegations Concerning the Merck and Mylan Cases Cannot Save Plaintiffs' Sham Litigation Claim

In the Second Amended Complaint, Plaintiffs now claim that Sanofi engaged in meritless litigation against Merck and Mylan to block follow-on competition for insulin glargine products. Second Am. Compl. ¶¶ 11, 404-24, 430-35, 444-45, 450. Ranging from completely conclusory to demonstrably false, these allegations bring Plaintiffs no closer to stating a plausible sham litigation claim.

First, Plaintiffs' conclusory assertion that Sanofi's lawsuits against Merck and Mylan are "just as meritless as Sanofi's suit against Lilly," Second Am. Compl. ¶ 11, is devoid of *any* factual support. Plaintiffs do not even attempt to allege that Merck's and Mylan's products do not infringe the patents asserted. Instead, Plaintiffs note only that after receiving Paragraph IV certifications from Merck and Mylan, Sanofi objected to the confidentiality provisions the infringing companies sought as a precondition to providing portions of their NDAs to Sanofi. *Id.* ¶¶ 409-10, 432-33. Needless to say, that allegation sheds no light on the objective merit of Sanofi's enforcement of its intellectual property rights.

Second, the allegations of the Second Amended Complaint and the Merck and Mylan litigation dockets show that Plaintiffs cannot state a plausible sham litigation claim for either matter. Both suits were filed in response to Paragraph IV certifications, *see id.* ¶¶ 405-11, 430-34, which constitute statutory acts of infringement and provide "an objectively reasonable basis to sue." *See AstraZeneca*, 2010 WL 2079722, at *4. Plaintiffs do not allege that the patents Sanofi asserted have been declared invalid or unenforceable. And the Merck case—like the Lilly case—has been actively litigated for over a year and involved a claim construction hearing that upheld Sanofi's interpretations of a number of claims. *See Sanofi-Aventis U.S. LLC, et al. v. Merck Sharp & Dohme Corp*., No. CV 16-812-RGA, 2018 WL 389183 (D. Del. Jan. 12, 2018);

see also AstraZeneca, 2010 WL 2079722, at *4 (explaining that "[h]ard-fought and close" cases "hardly bespeak[] baseless litigation"). Further, both lawsuits are still pending and may well be resolved in Sanofi's favor, precluding a plausible claim that the cases lacked objective merit. *See Darba Enterprises, Inc. v. Amica Mut. Ins. Co.*, No. 2:12-CV-00043-LRH, 2012 WL 3096709, at *3 (D. Nev. July 30, 2012) (dismissing complaint where alleged sham litigation was "ongoing and has not been dismissed").

Finally, the Lilly, Merck, and Mylan cases do not constitute an actionable "pattern of baseless, repetitive claims," *see Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972), as a matter of law. As set forth at length above, Plaintiffs have not pleaded any actionable facts to support one sham litigation claim, let alone three.[17] Nor have plaintiffs satisfied their burden to plead that Sanofi's suits "provided no reasonable prospect of a benefit to [Sanofi] apart from inflicting costs on [defendants]." *Puerto Rico Tel. Co., Inc. v. San Juan Cable, LLC*, 874 F.3d 767, 772 (1st Cir. 2017) (holding that a pattern of 24 petitions that were not objectively baseless did not support a sham litigation claim as a matter of law). Rather, if Sanofi prevails, it will be able to protect its intellectual property until 2024, well beyond the life of the litigation. *See* Second Am. Compl. ¶ 251.

Moreover, while the exact number of lawsuits necessary to trigger "pattern" liability is a subject of debate, the case law is clear that three lawsuits do not suffice. *See, e.g.*, *Polaris Indus. Inc. v. Arctic Cat Inc.*, No. CV 15-4475, 2017 WL 1180426, at *6-7 (D. Minn. Mar. 29, 2017) (holding that three lawsuits are insufficient to constitute a "series" or "pattern" of proceedings); *Toyo Tire & Rubber Co. v. CIA Wheel Grp.*, No. SACV 15-246-JLS (DFMx), 2015 WL

[17] *See Puerto Rico Tel. Co.*, 874 F.3d at 777 (Barron, J., concurring) ("[N]o circuit has actually permitted a suit to go forward in which the underlying petitions were not baseless and there was no clear and convincing evidence that an alleged monopolist sought to use the governmental process as an anticompetitive weapon. And for good reason, given the First Amendment interests at stake." (internal quotation marks and citations omitted)).

4545187, at *3 (C.D. Cal. July 8, 2015) (same); *Rubloff Dev. Grp., Inc. v. Supervalu, Inc.*, No. 10 C 3917, 2013 WL 441152, at *3 (N.D. Ill. Feb. 5, 2013) (same); *Puerto Rico Tel. Co. v. San Juan Cable LLC*, 885 F. Supp. 2d 534, 538 (D.P.R. 2012), *on reconsideration in part*, No. CIV. 11-2135 GAG, 2012 WL 4052018 (D.P.R. Sept. 13, 2012) (same). Plaintiffs' allegations are therefore inadequate to state a plausible sham litigation claim for any one or all of the Lilly, Merck, and Mylan cases.[18]

In the Order, the Court observed that "[t]he sham litigation exception to the *Noerr Pennington* immunity was not intended to provide all third parties with an opportunity to re-litigate cases. Rather, the doctrine is reserved for those cases where plaintiffs can assert facts showing that the patent suit was objectively meritless." Order at 29. Plaintiffs have now failed that test twice, and their sham litigation claim must be dismissed with prejudice.

C. Plaintiffs' Claims Still Fail for Lack of Causation

Plaintiffs' pleading failures are most pronounced with respect to causation. Plaintiffs did not plead facts in the First Amended Complaint to show that "listing the '864 patent in the Orange Book was unreasonable, or that the litigation enforcing the '864 patent was a sham," and thus could not circumvent the fact that the patent "stood as a lawful bar to entry during the period of the alleged harm." Order at 32. The Second Amended Complaint contains no new facts to affect the Court's conclusion that Plaintiffs' claims fail for lack of causation.

[18] Because Plaintiffs have failed to plausibly allege that Sanofi's patent litigation was objectively baseless, any allegations regarding Sanofi's subjective motivation are irrelevant to assess the adequacy of their sham litigation claim. *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503-DJC, 2015 WL 5458570, at *11 (D. Mass. Sept. 16, 2015) (holding that because plaintiffs "have not stated a plausible claim that [defendant's] patent litigation was objectively baseless, [the court] need not reach the [second] prong of the sham litigation claim"). It is well-established that "[o]nly if [a] suit is found to be objectively baseless may the court proceed to the second prong of the [sham litigation] test," and consider whether the litigation was subjectively motivated by the defendant's intent to interfere with a competitor's business. *Morton Grove Pharm.*, 2006 WL 850873, at *10; *Prof'l Real Estate Investors, Inc.,* 508 U.S. at 60. Having failed to satisfy the first prong of a sham litigation test, Plaintiffs' claim can go no further.

Sanofi asserted the '864 patent in the Lilly litigation and the Mylan case. Second Am. Compl. ¶¶ 406, 411, 434. The Court concluded that the patent served as a lawful bar to entry against Lilly, Order at 32, and other pen patents stand as a lawful bar to Merck and Mylan's entry for all the same reasons.[19]

In addition, the FDA's failure to grant tentative approval to Mylan's insulin glargine product, *see* Second Am. Compl. ¶ 453, serves as an independent barrier to Mylan's ability to market and sell its insulin glargine product, and precludes Plaintiffs from plausibly alleging that Sanofi's lawsuit has caused any antitrust injury. *See, e.g.*, *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368 (S.D. Fla. 2004) ("[W]ithout tentative FDA approval, a generic manufacturer cannot enter the marketplace, and thus there is no antitrust injury."); *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 63 (D. Mass. 2003) (holding that prior to receiving tentative FDA approval, injury is "entirely speculative"); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000) (holding that plaintiff had not suffered antitrust injury and lacked standing because "[w]ithout tentative FDA approval, [counterclaim plaintiff] could not now enter the market, regardless of the pending [patent] litigation"); *see also In re Solodyn*, 2015 WL 5458570, at *9 ("Without a plausible allegation of delay caused by Defendants, the direct purchasers have not alleged a cognizable antitrust injury."). Absent "a plausible argument for causation," Order at 32, Plaintiffs' claims must be dismissed again.

[19] Although Sanofi dropped its claim against Merck for infringement of the '864 patent, it continues to assert infringement claims with respect to other pen patents, including patent numbers 8,603,044 ("the '044 patent") and 8,679,069 ("the '069 patent"). Second Am. Compl. ¶¶ 252, 310, 354, 406, 411, 434. Each of these patents protect a "Pen-Type Injector" that permits an adjustable "injection of medicinal products from a multidose cartridge," commonly used to "conduct effective management of . . . diabetes." Second Am. Compl. Ex. J at 11, Ex. M at 11. It was not unreasonable for Sanofi to list these injector-pen patents in the Orange Book for all the same reasons it was not unreasonable for Sanofi to list the '864 patent in the Orange Book, and Plaintiffs have failed to plausibly allege that asserting these patents against Merck was objectively baseless. The '044 and '069 patents thus "stood as a lawful bar" to Merck's ability to market and sell insulin glargine products, breaking the chain of causation between any allegedly anticompetitive activity and Plaintiffs' purported harm.

D. The Second Amended Complaint Should Be Dismissed for Failure to State a Plausible Relevant Market Within Which Sanofi Has Alleged Market Power

To prevail on their claims Plaintiffs must first plead and then prove market power in a relevant product market. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). The relevant market allegations in the Second Amended Complaint are virtually identical to those in the First Amended Complaint, save for a single paragraph that purports to describe the differences between insulin glargine and other insulin products. Second Am. Compl. ¶ 463. Plaintiffs do not explain how or why those differences impact reasonable interchangeability (the touchstone for ascertaining products that belong in a single market), and they come no closer to alleging a plausible relevant market because "illegal monopoly does not exist merely because the product said to be monopolized differs from others." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 394 (1956). For this reason, and for all the reasons set forth in the relevant market arguments in Sanofi's motion to dismiss the First Amended Complaint, *see* Def.'s Mem. in Supp. of Mot. to Dismiss at 23-29 and Def.'s Reply Mem. in Supp. of Mot. to Dismiss at 16-21, adopted and incorporated by reference herein, Plaintiffs have failed to allege that Sanofi had monopoly power within a relevant market. Consequently, the Second Amended Complaint should be dismissed with prejudice.

V. CONCLUSION

Plaintiffs have not added any actionable facts to their Second Amended Complaint and still cannot state a claim that Sanofi improperly delayed competition for Lantus and Lantus SoloSTAR products. Listing pen patents in the Orange Book was not improper or anticompetitive; Sanofi's patent litigation with Lilly was objectively reasonable and immune from antitrust liability; Plaintiffs cannot assert injury caused by anticompetitive conduct since the pen patents stood as independent and lawful bars to follow-on competition for Lantus; and

Plaintiffs' conclusory allegations of a single drug relevant market do not cross the pleading threshold. For all of these reasons, Plaintiffs Second Amended Complaint should be dismissed with prejudice.

Dated: March 16, 2018

By: */s/ Julie E. McEvoy*

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CERTIFICATE OF SERVICE

I, Laura Diss Gradel, hereby certify that a true copy of the foregoing document filed through the ECF system will be electronically sent to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on March 16, 2018.

Dated: March 16, 2018

/s/ *Laura Diss Gradel*
Laura Diss Gradel